

of the application, in which case they often must be deleted. It is therefore requested that this suggestion of the Examiner be withdrawn.

The Examiner's rejection under 35 U.S.C. §101 as reciting on the non-statutory subject matter has been overcome by an appropriate amendment to Claim 1.

The Examiner has objected to certain language in those claims calling for ambient sound sensing means in the vicinity of the patient. In a telephone conference with the Examiner on November 5, 1999 it was pointed out that applicant believed this to be an apt term because it denotes the state of being near or close by and/or that it is positioned in the area surrounding a particular place. In order to be useful, the ambient sound sensing means must be in the vicinity of the patient. It is submitted that "in the vicinity of" should be an acceptable term because to monitor sounds which are not in the vicinity of the patient in which the patient could hear the sounds would be of little or no value. It is therefore respectfully submitted that the Examiner's objection to this term should be withdrawn.

The Examiner has rejected Claims 1-16 under 35 U.S.C. §103(a) as being unpatentable over Sullivan et al. in view of Scanlon. Sullivan et al. 5,522,382 discloses a device and method for treating obstructed breathing and utilizes a nose piece 12 which controls the entire flow of air into and out of the nose of the patient. A microphone 11 is used on the nose mask and is connected to an electronic processor/recorder which records signals from the microphone 11. This information is used for driving a CPAP apparatus whereby when a snore or sequence of snores is detected by the snoring detection means, a signal is generated to cause the control unit 23 to increase the speed of the fan motor and its output pressure. This process is repeated until the upper airway is stabilized and snoring ceases. Thus it can be seen that all that Sullivan et al. discloses is a microphone for detecting snoring and for driving a CPAP apparatus to stop such snoring. Sullivan et al. merely discloses a block 26 in Figure 4 which is identified as an amplifier/filter/processor unit 26. There is nothing in the specification nor in the block 26 to identify what is included in this block. It certainly does not specifically include A to D conversion means. Nor does it have any means for estimating air volume inhaled and exhaled, nor any means for separating the apnea and hypopnea categories. First in Sullivan et al. there is no need for estimating air volume because all of the air volume passing through the nose of the patient is contained by the nose mask 12. With respect to apnea and hypopnea, this is

merely identified in col. 13, line 57, which merely states that the sound and breathing patterns can be analyzed by a programmed microprocessor or computing system as shown in Fig. 12 (col. 13, lines 59-61). However, again there are no details as to how this can be accomplished. It is merely a statement of a desire with no specifics. Rather all that is specifically shown in Figure 12 is a control for a motor blower to provide the CPAP to the patient.

Applicant in the present invention has designed a sophisticated apparatus to overcome the measure of difficulties using electronics for separating disordered breathing into apnea and hypopnea categories. Such means as disclosed in the claims certainly is not disclosed or suggested by Sullivan et al.

The Examiner in attempting to overcome these deficiencies of Sullivan et al. attempts to rely upon Scanlon 5,853,005 which discloses an acoustic monitoring system in which a transducer in communication with a fluid in a pad is held in close contact with the body of the patient. The electrical output from the transducer is disclosed as being capable of being filtered, amplified, analyzed or transmitted by a system 13. Scanlon then states that traditional diagnostic methods such as listening to an audio output and looking at a voltage-versus-time waveform can be augmented by joint time-frequency domain analysis techniques, neural networks, wavelet based techniques or template matching. There again there is just a catalog of devices which can be utilized but with no disclosures as to how they can be implemented to provide such a system. Thus it is respectfully there is no teaching either in Sullivan et al. or Scanlon of how one skilled in the art could make and build apparatus and perform a method which is capable of achieving the desired results as taught by applicant. Stated in other words, even combining the teaching of Sullivan et al. and Scanlon provides no teaching as to how applicant's desired results can be achieved.

Contrary to the suggestions of the Examiner, there is no teaching in Scanlon how the apparatus and method called for in the claims can be implemented. As will be noted from the specification and drawings and from the claims, applicant is claiming a very specific apparatus in which a considerable research and development effort has been undertaken to provide a workable apparatus and method. The mere blanket statements appearing in Sullivan et al. and Scanlon suggesting that certain results can be achieved without describing how they can be

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achieved certainly does not show or suggest to one skilled in the art how such apparatus and the method claimed by applicant can be performed.

Many of the elements called for in the apparatus claims and the steps called for in the method claims are not disclosed or suggested by the references. For example, Claim 1 calls for means for operating on the filtered air flow information for estimating the amount of air volume inhaled and exhaled by the patient to provide a signal representing the estimated volume of air. Such means certainly is not disclosed by Sullivan et al. because as pointed out above Sullivan et al. controls all of the air flow into and out of the nose of the patient by the nose mask 12. Similarly in Scanlon, there is no suggestion that there is any attempt to provide an estimated volume of air flow. Certainly the overall combination called for in Claim 1 is not shown or suggested by the references. It is therefore submitted that it is patentable over the references.

Claims 2-10 include the subject matter of Claim 1 and are patentable for the same reason as Claim 1. They also call for additional elements which are not shown or suggested by the references cited.

The Examiner relies upon Sullivan et al. to disclose active noise cancellation for suppressing the background noise. The Examiner relies on col. 8, line 58 of Sullivan et al. which discloses use of an amplitude filter to effectively ignore all sounds below a particular minimum amplitude by passing the signals through a low pass frequency filter. Thus it can be seen that all that Sullivan et al. discloses is the use of a passive filter. This is not active noise cancellation means as called for in Claim 4. Applicant's active noise cancellation means includes an adaptive filter which models the acoustical transfer function and suppresses the background noises actively. Passive filtering means such as disclosed by Sullivan et al. would be ineffective in the present application because there is often an overlap between noise frequency and respiration signal frequency. For that reason as called for in Claim 4 it is necessary to utilize active noise cancellation with adaptive filtering.

Claim 11 is an independent method claim and it also calls for estimating the air volume inhaled and exhaled by the patient and other specific steps which are not disclosed or

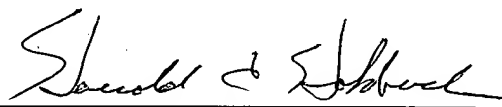
suggested by the references cited. It is therefor respectfully submitted that Claim 11 is allowable.

Claims 12-16 include the subject matter of Claim 11 and are patentable for the same reason as Claim 11. They also call for additional steps which are not suggested by the references cited.

In view of the foregoing, it is respectfully submitted that the claims are in condition for allowance and that the application should be passed to issue.

Respectfully submitted,

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